

REMARKS

Applicant has made amendments to the claims pursuant to the Examiner's rejections and requests reconsideration of the application of the present invention. Upon review of the specification, Applicant became aware of a typographical informality. Table 2 is the specification has been amended to correct such informality. Table 2 is specifically set forth to disclose the loss of water from magnesium upon heating. As provided in the original disclosure, the number "1" was inadvertently omitted and resulted in values of "00°C" and "20°C", instead of stating "100°C" and "120°C", respectively. The correction does not add any new matter or alter the scope of the Table as originally filed, since the Table is provided to demonstrate "the loss of water form magnesium upon heating".

I. Rejection of Claims 1, 2, 4, and 9-11 under 35 USC 102(b) as being anticipated by Takaichi et al. (WO 96/22704)

Claims 1, 2, 4, and 9-11 stand rejected under 35 USC 102(b) as being anticipated by Takaichi et al. (WIPO Document No. WO 96/22704). Applicant respectfully traverses this rejection.

According to the Examiner, the Takaichi et al. reference discloses a method of stabilizing pharmaceutical compositions by the use of calcium oxide and particulate silicon dioxide to control moisture and restrict the interaction of water with other components of the compositions. Furthermore, the amount of calcium oxide to be included in the composition is not to exceed 1.0% by weight.

In contrast, the present invention discloses and teaches the combined use of calcium oxide and a magnesium salt to provide not only a desiccating effect but also a nutritional

supplement. The Takaichi reference makes no suggestion that magnesium salts should be used in combination with the calcium oxide. In addition, the present invention discloses a range of calcium oxide that is up to 10% by weight of the composition, and preferably from about 4-8% by weight of the composition. On the other hand, the Takaichi reference teaches that the amount of calcium oxide to be included in the composition is not to exceed 1.0% by weight of the composition. Therefore, the Takaichi reference teaches away from the present invention. The Takaichi reference suggests that calcium oxide can not exceed levels greater than 1% by weight of the composition, whereas, the preferred range of calcium oxide in the present invention is above 1%, more preferably 4-8% by weight of the composition.

In light of the above remarks, Applicant believes that the present invention is not anticipated by the Takaichi reference.

Applicant believes that the rejection has been removed and respectfully requests reconsideration by the Examiner.

II. Rejection of Claims 1, 2, 5, and 6 under 35 USC 103(a) as being unpatentable over Wilen

Claims 1, 2, 5, and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wilen (US Patent No. 2,297,599). Applicant respectfully traverses this rejection.

According to the Examiner, the Wilen reference, US Patent No. 2,297,599, teaches an effervescent pharmaceutical composition comprising dried magnesium sulfate, and an effervescent base, which may include sodium bicarbonate and citric acid (as seen in Example 2). The Examiner suggests that it would have been obvious to one skilled in the art to present magnesium sulfate in a quantity less than 10% by weight of the composition.

In general, the Wilen reference is concerned with effervescent tablets. In particular, Example 2, provides a tablet containing magnesium sulphate and calcium gluconate. The calcium gluconate does not provide the desiccating effect as provided by the calcium oxide of the present invention. More particularly, it would not have been obvious to substitute the calcium oxide component of the present invention in place of the calcium gluconate as provided in the Wilen reference. In contrast, the calcium oxide and magnesium sulfate combination of the present invention was specifically selected to provide not only a desiccating effect but also a nutritional supplement that works in combination to counter the effect that each salt can have on the intestinal track alone. Therefore, the combination of the magnesium sulfate and calcium oxide is key to the desired performance of the present invention.

In light of the amendments provided and the above remarks, Applicant believes that the Examiner's rejections have been removed and respectfully request reconsideration of the rejection.

III. Rejection of Claims 1, 2, 4, and 9-11 under 35 USC 103(a) as being unpatentable over Takaichi et al.

Claims 1, 2, 4, and 9-11 stand rejected under 35 U.S.C. 103(a) as unpatentable over the Takaichi et al reference. Applicant respectfully traverses this rejection.

As previously suggested by the Applicant, the Takaichi et al. reference teaches away from the present invention by suggesting that it is not desirable to use amounts of calcium oxide greater than 1% by weight of the composition. In contrast, the present invention suggests that the preferred range of calcium oxide is up to 10% by weight of the composition, more preferably in a range of 4-8% by weight of the composition. Therefore, the combination of calcium oxide

and magnesium sulfate in the denoted proportion as provided in the present invention would not have been obvious in view of the Takaichi reference.

In light of the amendments made and the remarks previously provided, Applicant suggests that the Examiner's rejections have been removed and respectfully request reconsideration of the rejection.

IV. Rejection of Claims 1-13 under 35 USC 103(a) as being unpatentable over Takaichi et al. in view of Wilen, Needleman et al, Theeuwes, and Buysch et al.

Claims 1-13 stand rejected under 35 U.S.C. 103(a) as unpatentable over Takaichi et al. in view of Wilen, Needleman et al, Theeuwes, and Buysch et al.

In light of the above remarks regarding the Takaichi reference and the Wilen reference, Applicant believes the Examiner's rejections have been removed. Neither the Wilen, Needleman, Theeuwes or Buysch references either alone or in combination with the Takaichi reference disclose or would suggest to one skilled in the art the combination of calcium oxide and magnesium sulfate as provided in the amended claims of the present invention. As disclosed on the bottom of page 2 to the top of page 3, the calcium oxide and magnesium sulfate are selected to counter each other in terms of their constipating and diarrhoeal effects. Furthermore, as provided on page 15 of the specification, the combined minerals can provide the end product with re-mineralizing concentrations of calcium and magnesium. The provided combinations of the present invention, as well as the desired effects, would not have been obvious based on the suggested references. Therefore, in light of the provided references, the combination of the calcium oxide and magnesium sulfate of the present invention would not have been obvious.

Applicant respectfully requests reconsideration by the Examiner.

V. CONCLUSION

In view of the foregoing amendments and submissions, Applicant respectfully requests that the rejection of pending claims 1-13 be withdrawn. Applicant requests consideration of the amended claims 1-13 and newly added claims 14-16. If the Examiner should have any questions, please contact the undersigned for any further clarification. Applicant hereby requests further consideration of the application.

Date 11/26/02

Respectfully submitted,

By: 

Robert L. Kelly

Reg. No. 31,843

Attorney for Applicant

Phone: 248-203-0849

Fax: 248-203-0763

DYKEMA GOSSETT PLLC

39577 Woodward Ave, Suite 300

Bloomfield Hills, MI 48304-2820

CERTIFICATE OF EXPRESS MAILING

I hereby certify that the enclosed Response is being deposited with the United States Postal Service as Express Mail No. ET931277133US, postage prepaid, in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231, on this 26th day of November, 2002.



Patricia A. Kniola

APPENDIX A
(Version with Markings to Show Changes Made)

TABLE 2

Loss of Water from Magnesium Heptahydrate on heating

Temperature °C No. of molecules of water lost

| | |
|------------------|---|
| Ambient | 1 |
| 70-80°C | 4 |
| 100°C | 5 |
| 120°C | 6 |
| 250°C (Calcined) | 7 |

APPENDIX B

(Version with Markings to Show Changes Made)

1. (Twice Amended) A nutritional or pharmaceutical composition comprising one or more water containing components in which the water is releasably bound wherein [at least one anhydrous compound is] CaO and anhydrous or calcined MgSO₄ are mixed in the composition in an amount capable of sequestering any water which may be released from the one or more water containing components to provide a continuous desiccant effect under normal handling conditions.
4. (Twice Amended) The composition according to claim [2] 1, wherein the CaO is present in an amount up to 10% by weight of the composition.
5. (Twice Amended) The composition according to claim [2] 1, wherein anhydrous or calcined MgSO₄ is present in an amount up to 10% by weight of the composition.
6. (Twice Amended) A composition as recited in claim 1, which further comprises an acid [or a salt thereof] component and a carbonate and/or bicarbonate [or a salt thereof] sufficient to cause said composition to effervesce in water.
7. (Twice Amended) A composition as claimed in claim 6, wherein said acid [or a salt thereof] component is calcium lactate.
8. (Once Amended) A composition as claimed in claim 1 further comprising a sulphite.
9. (Once Amended) A composition premix comprising an acid or salt thereof in admixture with CaO and anhydrous or calcined MgSO₄ [an anhydrous compound which has a greater avidity for water than the acid or salt thereof].
10. (Once Amended) The use of CaO and [or] anhydrous or calcined MgSO₄ in the manufacture of a nutritional or pharmaceutical composition for the purpose of effectively removing/mopping up adventitious water.
11. (Once Amended) A method of manufacturing a nutritional or pharmaceutical composition comprising one or more components which contain water which is releasably bound wherein the manufacturing steps are conducted in the absence of special low humidity conditions and CaO and anhydrous or calcined MgSO₄ [one or more anhydrous compounds] are intimately

mixed in the product in an amount capable of sequestering any water which may be released from water containing components to provide a continuous desiccant effect.

12. (Once Amended) The composition according to claim [3] 1, wherein the CaO is present in an amount up to 10% by weight of the composition.
13. (Once Amended) The composition according to claim [3] 1, wherein anhydrous or calcined MgSO_4 is present in an amount up to 10% by weight of the composition.
14. (New) The nutritional or pharmaceutical composition as claimed in claim 1 wherein CaO is present in an amount of from 4-8% by weight of the composition.
15. (New) The nutritional or pharmaceutical composition as claimed in claim 1 wherein the anhydrous or calcined MgSO_4 is present in an amount of from 1-5% by weight of the composition.
16. (New) The composition premix as claimed in claim 9 wherein the acid salt is calcium lactate.